

DETAILED ACTION

Responsive to communications entered 5/28/2009; 8/28/2009. Claims 5,44 and 50 are pending. Claims 5,44 and 50 are under consideration.

Priority

The present application was filed 7/2/2003. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) is acknowledged. This application claims benefit of provisional application(s): 60/394,176 filed 07/03/2002.

Withdrawn Objection(s) and/or Rejection(s)

The rejection of claim 50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement concerning new matter is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 5,44,46,50 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is hereby withdrawn in view of applicant's amendments to the claims.

The rejection of claims 5 and 44 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicant's amendments to the claims.

Maintained Claim Rejection(s) - 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection concerns new matter.

Claim 5 is now drawn to each D-peptide is from three to seven D-amino acid residues and wherein at least 68 % of the D-peptides comprise at least three aromatic residues selected from the group consisting of D-Trp, D-Tyr and D-Phe.

Applicant has successfully shown implicit support in the disclosure for the pentapeptide library built by split synthesis in paragraph 0049 (p13) of the present specification for wherein at least 68 % of the D-peptides comprise at least three aromatic residues selected from the group consisting of D-Tyr, D-Phe and D-Trp and two "spacer" residues of D-Ala and Gly, however applicant does not show 68 % with regard to three, four, six or seven residues.

The specification as originally filed provided no implicit or explicit support for at least 68 % of the D-peptides comprise at least three aromatic residues selected from the group consisting of D-Trp, D-Tyr and D-Phe and two "spacer" residues of D-Ala and Gly when the D-peptides are three, four, six or seven residues.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Response to Arguments

On p 6 of the response entered 5/28/2008, applicant argues at least 68% enrichment of at least three aromatic residues automatically occurs when building hexamer and heptamer libraries in the *same* manner as the pentamer library, exemplified in paragraph 0016 of the specification (i.e. utilizing five-way split synthesis adding one of D-Tyr, D-Phe, D-Trp, D-Ala and Gly to each tube); applicant calculates, a hexamer library would have 82 % enrichment and the heptamer library would have a 85 % enrichment, each at least 68% applicant asserts.

In this vein, it is noted that nowhere in the specification is it disclosed that the hexamer and heptamer libraries should be made with the same manner as the pentamer library. In fact, the specification in paragraph 0015 describes as little as 30 % enrichment of at least three aromatic residues as being suitable for libraries 3-7 amino acids.

On p 7 of the response entered 5/28/2008, applicant argues that a tetramer library made with four-way split synthesis adding one of D-Tyr, D-Phe, D-Trp , D-Ala or Gly would provide a tetramer library with 189/256 or 74% enrichment.

In this vein, nowhere in the specification is it disclosed split synthesis should be made with only four residues in building the tetramer library, as opposed to five-way split synthesis, such as used in preparing the pentamer discussed above. A five-way split synthesis would provide a tetramer library with 297/625 or only 48% enrichment. Also outside the range, as mentioned above, suitable libraries of 3-7 amino acids according to specification paragraph 0015 may contain as little as 30 % enrichment of at least three aromatic residues.

On p 7 of the response entered 5/28/2008, applicant argues that a trimer library made with a three-way split adding one of D-Tyr, D-Phe, D-Trp would provide a tetramer library with 100% enrichment.

In this vein, nowhere in the specification is it disclosed the split synthesis of the trimers should be three-way, as opposed to for instance the pentamer protocol discussed above with a five-way split, which would provide a tetramer library with 27/125 or only 22% enrichment (see also section 7 of 8/28/09 Martin Declaration).

On p 3 of the remarks entered 8/28/2009, applicant points to p 2 paragraph 0006 for support. This passage does not mention Gly or D-Ala spacers as currently claimed nor 68% enrichment.

On p 3 of the remarks entered 8/28/2009, applicant points to p 2 paragraph 0008 for support. This passage does not mention Gly or D-Ala spacers as currently claimed nor 68% enrichment.

On p 3 of the remarks entered 8/28/2009, applicant points to p 3 paragraph 0014 for support. This passage does not mention D-Tyr, D-Phe, D-Trp as aromatic residues or Gly and D-Ala spacers, nor 68% enrichment.

On p 3 of the remarks entered 8/28/2009, applicant points to p 3 paragraph 0015 for support. This passage does not mention D-Tyr, D-Phe, D-Trp as aromatic residues or Gly and D-Ala spacers. Notably, paragraph 0015 of the present specification states "For libraries of D-peptides having from three to seven amino acid residues... **as many as 50% or more** of the D-peptides comprise at least three or more aromatic D-amino acid residues." Emphasis added. This passage is interpreted as encompassing the entire range from 1-100% enrichment as desirable.

On p 3 of the remarks entered 8/28/2009, applicant points to p 5 paragraph 0020 for support. While this passage does mention D-Tyr, D-Phe, D-Trp as aromatic residues it does not discuss Gly and D-Ala as spacers or 68% enrichment

On p 4 of the remarks entered 8/28/2009, applicant points to original claim 5 for support. While this passage does mention D-Tyr, D-Phe, D-Trp as aromatic residues it

does not describe Gly and D-Ala as spacers and recites as little as 25% enrichment, again outside the range now claimed.

In conclusion, nowhere in the specification is 68% disclosed as constituting a desirable cut off for three or more aromatic D-amino acids selected from the group consisting of D-Trp, D-Tyr and D-Phe in libraries of 3,4,6 or 7 residues. Paragraph 0015, in fact recites the entire range from 1-100% enrichment as suitable. Nowhere does the specification describe hexamer and heptamer libraries made with the *same* five-way split synthesis scheme as the pentamers, much less with D-Tyr, D-Phe, D-Trp , D-Ala and Gly as currently claimed. Along the same line, in building the trimer and tetramer libraries, nowhere does the specification describe the pentamer protocol *modified* in the manner asserted by applicant to generate 68% enrichment of at least three aromatic residues selected from the group consisting of D-Trp, D-Tyr and D-Phe.

Response to Declarations

The declarations under 37 CFR 1.132 filed 8/28/2009 are insufficient to overcome the rejection of claims 5 and 44 under 35 USC 112 first paragraph as set forth above because the examiner does not deny the importance of the invention or deny the fact that the present disclosure is enabled for preparing the libraries currently claimed. The issue concerns evidence as to whether applicant conceived - at the time the invention was made - 3,4,6, or 7 residue libraries wherein 68% of the D-peptides consist of at least three aromatic residues selected from the group consisting of D-

tryptophan, D-tyrosine, and D-phenylalanine and the remaining residues are selected from the group consisting of glycine and D-alanine.

Vas-Cath Inc. v. Mahurkar, 19 USPQ 2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, **as of the filing date sought**, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See Vas-Cath at page 1117; emphasis added). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 116). As discussed in detail above, the skilled artisan cannot immediately envision 68% enrichment of D-peptides comprising at least three aromatic residues in the trimer, tetramer, hexamer and heptamer libraries based on the disclosure. This does *not* mean that the skilled artisan could not prepare such a library based on the disclosure, especially in concert with Lebl et al reference, cited in the application and mentioned by the declarants, but rather 3,4,6 or 7 residue libraries which are enriched with 68 % of three or more aromatic D-amino acids selected from the group consisting of D-Trp, D-Tyr and D-Phe and two "spacer" residues of D-Ala and Gly constitutes new matter, as one cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483.

New Claim Rejection(s) - 35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by applicant's amendments to the claims.

Claim 5 recites the limitation "the water based fluid phase" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites the limitation "the support" (singular) in line 44 whereas claim 5 to which claim 44 depends recites supports (plural). Accordingly there is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

Claim 50 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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